Testimony
Before the Subcommittee on Africa, Global Human Rights and International Operations
Committee on International Relations
United States House of Representatives

Activities Relating to Global Blood Safety at the Department of Health and Human Services

Statement of

Jerry A. Holmberg, Ph.D.

Senior Advisor for Blood Policy and
Executive Secretary, Advisory Committee on Blood Safety and Availability
Office of Public Health and Science
U.S. Department of Health and Human Services

For Release on Delivery
Expected at 2:00 p.m.
Tuesday, June 27, 2006

Good morning, I am Dr. Jerry Holmberg, Senior Advisor for Blood Policy and Executive Secretary of the Advisory Committee on Blood Safety and Availability within the Office of Public Health and Science of the Department of Health and Human Services (HHS). I am pleased to be here today to discuss blood safety and transfusion-transmitted diseases, including HIV/AIDS, viral hepatitis, and malaria in Africa. I have over 35 years of experience, primarily in clinical laboratory science, and have been involved in the blood community since the early 1970s, and I take blood safety and the availability of blood products seriously.

Sitting behind me today is my colleague from the Centers for Disease Control and Prevention (CDC), Dr. Matthew Kuehnert. Dr. Kuehnert is the Assistant Director for Blood Safety, Division of Viral and Rickettsial Diseases, National Center for Infectious Diseases, Centers for Disease Control and Prevention in Atlanta. I have asked Dr. Kuehnert to be present at this hearing to collaborate with me on questions you may ask.

Please permit me to state that in my official capacity, I participate internationally with the Global Collaboration for Blood Safety (GCBS). Recognition of the need for a GCBS was first endorsed by 41 countries represented during the Paris AIDS Summit in 1994 and adopted by the Forty-Eighth World Health Assembly (WHA) as WHA resolution 48.27 (1995), by all 191 World Health Organization (WHO) Member States in order to prioritize the need for global collaboration to improve blood safety. WHO is a participant of GCBS and also provides its secretariat.

The GCBS participants agree to collaborate in facilitating progress in the following areas:

- international consensus on essential principles of global blood safety;
- encouraging the recognition and establishment of national blood programs;
- identifying priorities for the prevention of transfusion-related disease;
- implementation of appropriate and recognized transfusion practices, which ensure donor and recipient safety and are free from discrimination;
- effective recruitment of safe donors through the use of appropriate selection criteria;
- assuring quality and safety in the preparation of blood and blood products;
- safe international practices for the collection, storage, and transport of plasma and the preparation and distribution of its derivatives;
- the bi-directional traceability of blood products between donor and recipient whether in-country or across national borders; and
- promote evidence-based use of blood and blood products
- the exchange and use of information by encouraging data collection, management and dissemination.

The GCBS represents some of shared concerns that the Committee has in regards to improving blood safety and the medical infrastructure in Africa.

In my remarks today, I will be addressing the overall burden of disease of HIV/AIDS, viral hepatitis, and malaria in sub-Saharan Africa, and the role that unsafe blood transfusions play in the transmission of these diseases. I also will discuss the barriers and challenges related to implementing a long-term, sustainable blood safety program in the developing world, and will conclude by discussing some of the Department's efforts to improve blood safety and address the burden of disease in sub-Saharan Africa.

HIV, Viral Hepatitis, and Malaria in sub-Saharan Africa

In the health care setting, HIV, the hepatitis viruses (hepatitis B virus (HBV) and hepatitis C virus (HCV)), and the parasites that cause malaria are easily transmitted through exposures to blood caused by unsafe injections, poor infection control practices, and contaminated blood. Yet, at present fewer than 30% of countries worldwide have fully functioning national blood transfusion services. The problem is especially acute in Africa, where an estimated 14 million blood units are needed, while only 3.6 million units were collected for distribution in 39 countries in 2004.[1] Improving access to safe blood in the developing world is a daunting challenge requiring development of sustainable infrastructure which is complex and resource- and time-intensive. I will address the barriers faced by many countries and the Department's response to them later in my testimony.

HIV/AIDS

Since 1981, AIDS has killed more than 25 million people, making it one of the most devastating epidemics in history. In 2005, AIDS killed three million people, with 80% of these deaths in sub-Saharan Africa. In addition, there were almost 5 million new HIV infections worldwide – more than 11,000 new infections every day – bringing the number of people living with HIV to more than 40 million (UNAIDS, 2005). Around the world, the vast majority of these infections are sexually transmitted. Intravenous drug use and perinatal transmission also account for significant numbers of infections. The cost in human lives lost is staggering. And there are important subsequent costs that accompany each new infection and each death. Persistent stigma and discrimination in much of the developing world mean infected people remain at risk of

[1] Global Database on Blood Safety, World Health Organization

losing jobs, friends, and family support. AIDS has torn apart families, orphaned children, and put new stresses on developing economies. For example, countries with an HIV prevalence of 15%, as is the case in a number of sub-Saharan African countries, are estimated to lose 1% Gross Domestic Product (GDP) every year[2].

Although blood transfusions account for a minority of new infections in countries with generalized epidemics (where most new infections are the result of heterosexual contact), contaminated blood remains the most efficient method of transmitting HIV from one person to another. According to WHO, transfusions are estimated as the cause of 5% of HIV infections in developing countries.[3] I must say that the prevalence may be higher since reporting, documentation, and investigation into causes of the HIV infection may be non-existent in these developing countries. Factors that contribute to transfusion-related transmission in sub-Saharan Africa and other parts of the developing world include: high rates of transfusion in some groups of patients (particularly women and children); a higher prevalence of HIV in the general and blood donor populations; inadequate HIV antibody screening in some countries; and a high residual risk of contamination in blood supplies despite antibody screenings.

Viral Hepatitis

Much of the worldwide viral hepatitis burden, which includes acute infections, chronic hepatitis, cirrhosis and liver cancer, is due to HBV. HBV kills about 620,000 persons worldwide annually. Approximately 350 million persons - 5% of the world's population - live with chronic HBV

[2] Pavon B (2004). AIDS Slashes Life Expectancy in 23 African Countries. UN Chronicle Online Edition, Issue 3.
[3] WHO. Blood Safety and Clinical Technology Progress 2000-2001, 2002.

infection, with the highest rates of transmission and chronic infection primarily in parts of Africa and Asia.

In sub-Saharan Africa, most of Asia, and the Pacific, most people become infected with HBV during childhood, and 8% to 10% of the general population is chronically infected. Young children who become infected with HBV are more likely to develop chronic infection. The risk of death from HBV-related liver cancer or cirrhosis is approximately 25% for persons who become chronically infected during childhood.

While less common than HBV as a cause of acute hepatitis, HCV is estimated to have infected about 170 million people, some 3% of the world's population, 130 million of whom are chronic carriers, according to WHO. Disease prevalence is high in many countries in Africa, Latin America and Central and South-Eastern Asia. In these countries, prevalence rates range from 5% to 10% (WHO).

Screening in general remains a challenge in many resource constrained countries. According to WHO estimates based on country reports, one-third of the 90 million units of blood transfused worldwide in 2000 were not screened for one of the three most serious transfusion transmitted viruses, HIV, HBV and HCV.[4] This gap in screening directly contributed to 78,000 HBV infections and more than half a million HCV infections.

In sub-Saharan Africa in 2000, more than 70% of blood donations were screened for HBV, but only about 10% were screened for HCV. The total number of infections attributed to unsafe

[4] Rapita, E. Dhingra N, Hutin Y, and Lloyd D. 11th International Symposium on Viral Hepatitis and Liver Disease. Syndey, Austraila, 2003.

blood donations was 30,000 for HBV and 52,000 for HCV, leading to 80 deaths from HBV infection and 440 deaths from HCV.

Although the overall proportion of new infections attributed to transfusion-transmitted HIV and viral hepatitis may be relatively low, because blood safety interventions are likely to be effective once they are implemented, they can be a potentially attractive preventive strategy. This, however, strongly depends on available resources and infrastructure for the interventions to be feasible.

Malaria

Malaria causes 300-500 million acute illnesses annually and kills as many as 1 million people, mostly children under five years of age, according to WHO. Almost half of the world's population lives in areas where malaria is endemic. In Africa alone, malaria is responsible for an estimated 25% to 35% of all outpatient visits and 20% to 45% of all hospita1 admissions. The economic impact associated with lost work days due to malaria has been estimated to reduce the GDP of heavily burdened countries by between 1% and 4%. The cost of these losses may be as high as US$12 billion per year.

In the case of malaria, mosquitoes, not blood transfusions, are the primary vector of infection. However, blood transfusions play a critical role in sustaining the lives of children suffering from malaria-induced anemia. Anemic children lack sufficient red blood cells to carry oxygen to their organs. In severe cases, these children require blood transfusion to survive – transfusions that are frequently unavailable due to a lack of blood.

Screening donors for malaria has not been a priority activity in the African context because:

- the overwhelming source of exposure to malaria in Africa is from infected mosquitoes rather than transfused blood;
- screening tests are not sufficiently sensitive to effectively identify and defer donors to prevent them from transmitting infection; and
- many children receiving blood transfusions in this setting are already being treated for malaria as the underlying cause of their severe anemia.
- in many countries where malaria has high prevalence, standard protocol is to treat all transfusion recipients for malaria.

Additionally, because of high rates of malaria among potential donors, screening would further diminish an already inadequate blood supply.

Issues related to blood safety in developing countries

In the United States, the blood supply is considered very safe. The risks of infection with known blood-borne pathogens are low because of extensive donor exclusion guidelines, including laboratory screening. The medical transfusion community maintains continuously improved efforts to collect blood only from the safest donors and to screen all donated blood for blood-borne pathogens. The safety of the blood supply in the developing world, however, is markedly different than that in the United States.

Barriers to maintaining an adequate, safe blood supply in developing countries exist on many levels. In many sub-Saharan Africa countries, blood services are either non-existent or significantly under-resourced or lacking the infrastructure and capacity to ensure sustainable

operations. Infrastructure challenges include problems with electricity to ensure the consistent refrigeration needed to store donated blood. Additionally, funding is frequently inadequate to purchase blood-banking equipment and test kits, especially in countries faced with extreme poverty, political instability, and armed conflict. Also, in these same countries, salaries and training for blood-banking and transfusion personnel may not be supported by the national budget.[5] This is particularly true in countries lacking policies and legislation for blood safety. In addition, many hospitals do not have effective laboratories to ensure the complete screening of blood. In countries with a high prevalence of HIV, HBV, and HCV among blood donors, this risk is especially high. Consequently, an incremental and time-phased approach that establishes the political, medical, and logistical frameworks for transfusion services is recommended.

Regular, unpaid voluntary blood donors are needed for high-quality blood services worldwide – but identifying and targeting low-risk volunteers for blood donations can be difficult in areas with high disease prevalence. Currently, volunteer donors provide less than half of the blood supply in developing countries, and few countries have mobilized efforts to encourage unpaid, voluntary blood donation. In many countries where cultural attitudes may limit the acceptance of blood donation activities, governments and other institutions are beginning to counteract these attitudes with educational outreach programs.

Still, many countries are forced to rely on emergency blood donations from paid donors or family members. These so-called "replacement" donors carry an increased risk of transmitting disease. Based on findings that unpaid donors have the lowest risk of transfusion-transmitted

[5] Clark, KA. Pediatric Transfusion in Developing Countries. In: Hillyer, Strauss and Luban, editor. Handbook of Pediatric Transfusion Medicine. San Diego, CA: Elsevier Academic Press; 2004. p. 149-157.

viruses, the WHA adopted Resolution WHA 28.72 in 1975 and WHA 58.13 in 2005, which urged all WHO member states to base national transfusion services on non-remunerated volunteer blood donors.

Limited amounts of safe and volunteer-donated blood, poor infrastructure (including a lack of clean water and constant electricity), and structural limitations in the healthcare system all contribute to the need for an integrated health and development strategy to ensure blood safety. Achieving a high quality, sustainable public health response will require implementing and strengthening multiple systems, including clinical quality assurance systems; health care infrastructure; human resource development; and procurement and logistics systems.

Current HHS/CDC activities relevant to blood safety and prevention

There are a group of activities at HHS/CDC that impact the safety of blood in Africa. I want to highlight a few of these, including three of the most relevant programs.

As part of the President's Emergency Plan for AIDS Relief (Emergency Plan), HHS/CDC actively supports the development of integrated strategies for blood safety in 14 of the 15 focus countries,[6] 12 of which are in sub-Saharan Africa. HHS/CDC's Emergency Plan-funded initiative pairs the National Blood Transfusion Services with one of five non-governmental organizations[7] that are recognized leaders in blood safety. This approach allows local blood

[6] Botswana, Côte d'Ivoire, Ethiopia, Guyana, Haiti, Kenya, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Tanzania, Uganda, and Zambia. Vietnam was recently added as the 15th country.

[7] American Association of Blood Banks (AABB), Safe Blood for Africa Foundation, Sanquin Consulting Services, Social and Scientific Systems, Inc. (SSSI), and World Health Organization (WHO/PAHO).

services to obtain world class expertise and provides their personnel to the latest training. At the same time, it ensures that ideas, policies, and strategies are developed at the local level, with national staff serving in key leadership roles. This approach has four elements:

1. Enhancing local laboratories' capacity to test all donated blood for transfusion transmitted infections, with an emphasis on quality-assured screening of all donated blood for HIV.
2. Promoting voluntary non-remunerated blood donations – the collection of blood from, regular, unpaid blood donors from low risk populations.
3. Providing training and education for local medical personnel to reduce the number of unnecessary transfusions, promote safe and rational blood utilization, and increase the use of alternatives to transfusions.
4. Identifying the amount of blood needed each year to ensure a sufficient supply in each country.

HHS/CDC's experience in 14 countries has demonstrated that most countries cannot effectively utilize large increases in financial resources for blood safety, and that moderate increases which enable incremental scale-up are most appropriate.

HHS/CDC also provides subject matter expertise in the prevention of hepatitis B and C infection to community organizations, government agencies, and blood banks responsible for blood safety. It also develops evaluation panels for use internationally to determine the performance of test kits manufactured in other countries for laboratory screening of blood donations for HBV and HCV infections. Additionally, HHS/CDC provides financial support and

technical assistance to the WHO for blood safety and the prevention of HBV and HCV transmission in health care settings.

HHS/CDC is also involved in malaria prevention activities through the Presidential Malaria Initiative (PMI). The PMI is focused on expanding access to proven intervention methods like insecticide-treated bednets and indoor residual spraying, as well as scaling up access to effective care and treatment, especially for children and pregnant women.

These efforts help prevent cases and decrease the need for transfusions related to malarial anemia. As such, HHS/CDC is currently focused on making progress in reducing the enormous background rate of infection. Once this is achieved, blood safety activities as they relate to malaria could become more feasible and cost effective.

The National Heart, Lung, and Blood Institute (NHLBI) at HHS's National Institutes of Health supports epidemiological studies at international demonstration sites addressing important blood safety and availability issues to ensure a safe and adequate blood supply. NHLBI is in the process of expanding the study to several sites in developing countries, where researchers will investigate critical scientific issues related to transfusion-transmitted HIV and other established and emerging transfusion-transmitted agents.

Next steps

To summarize, for persons with HIV, viral hepatitis, or malaria in Africa, transfusion-associated transmissions represent a small proportion of the total number of new infections each year, but

the number of these transmissions is substantial nonetheless, and efforts to address these causes are an important component of a comprehensive prevention strategy. The creation of a blood safety program requires that attention be paid to issues of sustainability. Strategies must ensure that each new service is supported by adequate infrastructure such as laboratories and reliable power; that staff is recruited, trained, and retained; that laboratory equipment and reagents are appropriate and available; and that processing procedures are properly managed.

These are huge challenges. Yet despite these barriers, US Government support for blood safety programs is worthwhile for three reasons:

- First, proven interventions are available to dramatically reduce or virtually eliminate transfusion-related transmission of these infections.
- Secondly, blood safety programs protect vulnerable populations. Persons in need of transfusion cannot take personal action to reduce their risk.
- Third, blood safety programs build public health capacity by raising standards of care and building technical capacity among laboratory workers, nurses, and physicians. In addition, education, risk assessment, and laboratory screening can be used to support prevention interventions to other at-risk populations and the general public.

CDC has had a leadership role in global blood safety since the early years of the AIDS epidemic, with extensive expertise in epidemiology, laboratory development and management, and scientific and technical training. CDC also has experience in developing and implementing infectious disease control programs domestically and internationally. In addition, CDC has conducted landmark epidemiologic investigations in a number of settings to establish the risk

for transfusion-associated infections; CDC scientists have devised and assessed new tests to protect the blood supply and have developed panels of specimens for blood banks to evaluate the quality of their screening of blood donations.

HHS supports the development of long-term, sustainable blood safety programs in Africa and Asia through the Emergency Plan and other initiatives. HHS and its agencies, such as CDC and the Food and Drug Administration, also have long standing relationships with WHO and other international organizations committed to blood safety.

Responding to the need to produce an adequate and safe blood supply in developing countries requires a comprehensive and coordinated effort among Ministries of Health and experts in blood transfusion throughout the world. Efforts implemented as part of the Emergency Plan have begun to address this need with a thorough and comprehensive approach that will produce immediate results, long-term improvement, and the likelihood of sustainability.

It is important to ensure that blood safety strategies are not only comprehensive, but integrated in or linked to other US Government-funded public health activities in a country. HHS works with its US Government partners and with other international health organizations to ensure that programs funded through various mechanisms, like the Emergency Plan, the Global Fund or private foundations, do not duplicate efforts. HHS/CDC country offices are actively engaged in seeking ways to partner with these external donors and designing projects to complement each organization's inherent strengths.

HHS and its agencies looks forward to continuing its collaborations with U.S. and international partners to incrementally strengthen the current blood safety program as part of a diverse portfolio of global disease prevention strategies.

Thank for you the opportunity to testify today. I am happy to answer any questions you may have.